

## REMARKS

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1-21 and 24-45 are now in the case. Claims 1, 3, 12, 24 and 39 have been amended. Claim 22 and 23 have been canceled. Applicants assert that the present amendment adds no new matter.

Applicants reserve the right to prosecute claims to canceled subject matter in one or more continuing applications.

### Claim Objections

The examiner objected to claims 1, 3, 12, 22, 23, 24 and 39 because of informalities and suggested that the claims be rewritten to better clarify the invention.

Claims 1, 3, 12, 24 and 39 have been amended as suggested by the examiner. Claims 22 and 23 have been canceled.

### Rejections Under 35 U.S.C. §112

The examiner rejected claims 1-45 under 35 U.S.C. §112, first paragraph because the specification while enabling for polynucleotide sequence of SEQ ID NO:1 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 1 to nucleotide 1682 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 1 to nucleotide 779 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 1 to nucleotide 833 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 1 to nucleotide 2887 or polynucleotide sequence of SEQ ID NO:834 [1 not 834] from nucleotide 1 to nucleotide 2887 polynucleotide sequence of SEQ ID NO:1 from nucleotide 126 to nucleotide 779 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 126 to nucleotide 833 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 834 to nucleotide 1682 or polynucleotide sequence of SEQ ID NO:1 from nucleotide 126 to nucleotide 1682 or nucleotide sequence encoding SEQ ID NO:2 from amino acid 20 to amino acid 237 or nucleotide sequence encoding SEQ ID NO:2 from amino acid 20 to amino acid 255 or nucleotide sequence encoding SEQ ID NO:2 from amino acid 256 to amino acid 538 or nucleotide sequence encoding SEQ ID NO:2 from amino acid 20 to amino acid 538 or polynucleotide sequences complementary, does not reasonably provide enablement for all possible nucleotide fragments contemplated by the Applicant. The examiner further asserts that the claims also recite the phrases "a polynucleotide sequence" and "a polypeptide" and thus, are broadly interpreted by the examiner as reading upon: (i) fragments of SEQ ID NOs:1-2, including sequences only 10 amino acids or 60 nucleic

acids in length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as claimed.

The examiner has also rejected claims 1-45 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejections. In making these rejections, the examiner has unreasonably interpreted the claims broadly as reading upon any and all fragments of SEQ ID NOS: 1 and 2, provided those sequences are 10 amino acids or 60 nucleotides in length. Relying on the same broad interpretation, the examiner also rejected the same claims for failure to meet the written description requirement under 35 USC §112, first paragraph.

The USPTO must employ the "broadest reasonable interpretation" standard for examining claims where such broadest reasonable interpretation must be "consistent with the specification". (See, MPEP 2111). The key word in this standard is "reasonable". Applicants contend that the interpretation of the claims to encompass any number of fragments of 10 or more amino acid residues from SEQ ID NO: 2 is not reasonable because it is not consistent with the use in the specification, that which was understood by those skilled in art, and the history of prosecution in family of patents from which this application arises.

The USPTO is unreasonably ignoring the recited sequence defined within the claim when interpreting the claim as reading upon "fragments of SEQ ID NO: 2, including sequences only 10 amino acids in length." The claims recite specific sequences, e.g. sequences consisting of residues 20-237, 20-255, 20-256, 20-538 of SEQ ID NO: 2. This plain language, previously understood to mean what it says, a polypeptide (or the polynucleotide sequence of SEQ ID NO: 1 encoding said polypeptide) consisting of amino acid residues 20-237, 20-255, 20-256, 20-538 of SEQ ID NO: 2, has been essentially rewritten to mean: a polypeptide of any ten amino acids present in SEQ ID NO: 2.

One consequence of interpreting the claims in this manner is that the longer the specified sequence is, the broader the claim actually is, which is not how claims are generally interpreted, nor how the claims were intended to be interpreted.

Moreover, Applicants contend that the USPTO's new interpretation of the contested claim language cannot be the "broadest reasonable interpretation consistent with the specification" and is consequently unreasonable because its interpretation manifestly ignores the context of the specification. The rejections under 35 USC §112, first paragraph, are based on the assertion the specification does not describe (written description) nor enable (enablement) fragments of SEQ ID NO:2. The examiner maintains that the specification merely invites one skilled in the art to further experiment because identification of the active site or binding site may not be sufficient to maintain activity. Applicants respectfully maintain that the examiner is incorrect in the assertions that applicants did not (1) provide teachings that provide guidance beyond just identifying a binding site, (2) attribute any function to the claimed protein, and (3) provide teachings for how to test for that function. The instant claims are directed to, and the specification discloses, polynucleotides encoding functional polypeptides. These include the secretory signal peptide of 19 amino acid residues (residue 1 (Met) to residue 19 (Gly) of SEQ ID NO:2); the mature polypeptide of 519 amino acids (residue 20 (Cys) to residue 538 (Ser) of SEQ ID NO:2); the WSXWS motif (SEQ ID NO:3) corresponding to residues 214 to 218 of SEQ ID NO:2, the cytokine-binding domain (residues 20 (Cys) to 237 (His) of SEQ ID NO:2); a domain linker (residues 120 (Pro) to 123 (Pro) of SEQ ID NO:2); a penultimate strand region (residues 192 (Lys) to 202 (Ala) of SEQ ID NO:2); a transmembrane domain (residues 238 (Leu) to 255 (Leu) of SEQ ID NO:2); complete intracellular signaling domain (residues 256 (Lys) to 538 (Ser) of SEQ ID NO:2) which contains a "Box I" signaling site (residues 267 (Ile) to 273 (Pro) of SEQ ID NO:2), and a "Box II" signaling site (residues 301 (Leu) to 304 (Gly) of SEQ ID NO:2). In addition to these domains, conserved receptor features in the encoded receptor include (as shown in SEQ ID NO:2) a conserved Trp residue at position 138, and a conserved Arg residue at position 201 are disclosed. The corresponding polynucleotides encoding the zalpha11 polypeptide regions, domains, motifs, residues and sequences described above are as shown in SEQ ID NO:1. These specific sequences are disclosed because these structural regions are known to be highly conserved within this cytokine

family providing structural characterization that guide the skilled artisan to make changes within the sequence that maintain functional aspects of the protein. Applicants submit that such disclosure constitutes the guidance that one skilled in the art would require to make and use the claimed invention.

Moreover, the biological function of polypeptides of the present invention are clearly described in the specification and include, for example: proliferation in BAF3 assays (Examples 7 and 8), competition assays (Example 12), antibody binding assays (Example 18) Applicants assert that the examiner is incorrect in assuming that a skilled artisan would not know what function to test for.

While the specification includes a generic description that polypeptide fragments can be sequences only 10 amino acids (or encoded by 60 nucleotides), the invention must be viewed in the context of the entire specification and claims. When viewed in this manner, it is clear that when the intent was to describe fragments, shorter sequences are defined as such. For example, when polypeptides are intended to encompass functional fragments, e.g., the WSXWS motif (SEQ ID NO:3) corresponding to residues 214 to 218 of SEQ ID NO:2, the cytokine-binding domain (residues 20 (Cys) to 237 (His) of SEQ ID NO:2); a domain linker (residues 120 (Pro) to 123 (Pro) of SEQ ID NO:2); a penultimate strand region (residues 192 (Lys) to 202 (Ala) of SEQ ID NO:2); a transmembrane domain (residues 238 (Leu) to 255 (Leu) of SEQ ID NO:2); complete intracellular signaling domain (residues 256 (Lys) to 538 (Ser) of SEQ ID NO:2) which contains a "Box I" signaling site (residues 267 (Ile) to 273 (Pro) of SEQ ID NO:2), and a "Box II" signaling site (residues 301 (Leu) to 304 (Gly) of SEQ ID NO:2), that information is clearly conveyed. When the intent is to cover a longer sequence, that sequence is recited. The specification offers clear description and enablement of specific fragments sequences recited in the claims, and such sequences are identified based on scientific evidence and reasoning. Given a reasonable interpretation of the language consistent with the specification, claims directed to those specific sequences are clearly defined. The instant specification provides clear written support as well as sufficient disclosure and guidance for one of skill in the art to make and use the polypeptides of the present invention without undue experimentation, as required by 35 USC §112, first paragraph. Upon reading the specification and claims, those ordinarily skilled in the art would recognize that any claimed polypeptides are biologically functional as stated

within the specification. Consequently, it would be unreasonable for a skilled artisan, or the USPTO, to read "a sequence consisting of residues 20-237, 20-255, 20-256, or 20-538 of SEQ ID NO: 2", to include fragments as small as ten amino acids as an element of the claimed invention.

To summarize applicants' position, the Office has adopted an unreasonable and overly broad interpretation for claims to a genus of polynucleotides encoding polypeptides to a specific sequence of SEQ ID NO: 2. The Office has interpreted the claims to cover all polypeptides of at least ten amino acids. Applicants traverse the rejection of the claims because it based on an overly broad claim scope which has disregarded applicants' teachings, the actual data presented, and what would be considered a reasonable interpretation of the claim language. Applicants respectfully request the rejection be withdrawn and the claims be allowed.

#### **Rejections Under 35 U.S.C. §102**

The examiner rejected claims 1-45 under 35 U.S.C. §102(e) as allegedly being anticipated by Donaldson et al. (U.S. Patent No. 6,057,128, PTO1449 of 11/19/03).

Applicants traverse the rejection as it applies to claims 1-21 and 24-45. Claims 22 and 23 have been canceled and therefore the rejection as applied to those claims is now moot. Under 35 U.S.C. §102(e), for a prior art reference to anticipate a claim, every element of the claim must be included in a single reference. The instant claims are drawn to polynucleotides that encode polypeptides of SEQ ID NO:2 that consist of defined fragments: (a) fragments consisting of amino acid 20-237 of SEQ ID NO:2, (b) fragments consisting of amino acid 20-255 of SEQ ID NO:2, (c) fragments consisting of amino acid 256-538 of SEQ ID NO:2 and (d) fragments consisting of amino acid 20-538 of SEQ ID NO:2. These defined fragments are not described in the Donaldson et al. reference. Thus, the instant claims are not anticipated by Donaldson, because not all elements within the claims are disclosed in the reference.

Since this single Donaldson et al., reference does not teach every element of the claimed invention, it cannot anticipate the invention. Consequently, Applicants respectfully request that rejections of instant claims 1-21 and 24-45, under 35 U.S.C. §102(e) be properly withdrawn.

The examiner rejected claims 1-45 under 35 U.S.C. §102(e) as allegedly being anticipated by Presnell et al. (U.S. Patent No. 6,576,744).

Applicants: Scott R. Presnell et al.

Serial No.: 10/715,998

Filed: November 18, 2003

For: POLYNUCLEOTIDES ENCODING CYTOKINE RECEPTOR ZALPHA11

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U.S. Patent No. 6, 756,744, is derived from U.S. Patent Application Serial No. 09/404,641, from which the instant application is a divisional application. A proper rejection under 35 USC §102(e) applies when an invention was described in a patent granted on an application for patent by another filed in the United States. Thus, applicants respectfully request that the examiner withdraw the rejection.

### **Double Patenting**

The examiner provisionally rejected claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-36 or copending Application No. 11/537,874.

The Examiner rejected claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 or copending Application No. 11/537,874. This is a provisional rejection because the conflicting claiming have not in fact been patented. Therefore, upon notice that the instant claims and conflicting claims are patentable, a Terminal Disclaimer, which Applicant believes overcomes the obviousness-type double patenting rejection will be filed. This Terminal Disclaimer will be filed solely for its statutory function of removing the rejection of double patenting and should not be regarded as an acquiescence in the merits of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 874, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991).

The examiner provisionally rejected claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/537,879.

The Examiner rejected claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims over claims 1-7 of copending Application No. 11/537,879. This is a provisional rejection because the conflicting claiming have not in fact been patented. Therefore, upon notice that the instant claims and conflicting claims are patentable, a Terminal Disclaimer, which Applicant believes overcomes the obviousness-type double patenting rejection will be filed. This Terminal Disclaimer will be filed solely for its statutory function of removing the rejection of double patenting and should not be regarded as an acquiescence in the merits of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 874, 20 USPQ2d 1392, 1394-95 (Fed. Cir. 1991).

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application

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and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6672.

It is believed that no fee is due. However, in the event that a fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,



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